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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/846,565

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05/29/2008

EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/846,565	Applicant(s) WINTERS, R. EDWARD	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-13 and 15-18 have been considered but are moot in view of the new ground(s) of rejection.

The examiner has responded to the applicants arguments to the Brown rejection, since the rejection has been maintained. The applicant has argued that Brown does not disclose the claimed coil spacing. The examiner disagrees and points applicant to fig.1A, which shows a larger spacing in a central section. Brown also discloses the ability to vary spacing of the coils to adjust the amount of blood flow (col.5, lines 7-10). The applicant has also argued that Brown's device is not capable of holding open a vessel. The examiner disagrees. Brown clearly shows the device anchored against a vessel wall (fig.7, 8). Brown's device is for placement vessel and thus is *capable* of placement in any vessel and will provide support for the vessel wall. Brown discloses anchorage and securment against vessel walls (col.4, lines 45-47; col.5, lines50-59).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9-11, and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 9 each recite the ends of the hoop to be uniformly spaced.

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Support was not found for a central larger spacing inbetween ends that are uniformly spaced. In fact, no support in the specification was found for the claimed spacing at all. Figures 11 and 12 seem to possibly show a greater spacing at the branch vessel, however the drawings are hand drawings and it is not clear of exact spacings, one can not determine if the ends would be uniform or not. Claims 2-4 and 10-11 depend upon claims 1 and 9 and inherit all problems associated with the claims.

Claim 15 recites an open space within the hoop and a spacing less than the open space. An open space in the hoop was not found by the examiner to be supported in the specification. Claim 16 depends upon claim 15 and inherits all problems associated with the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US 6,093,199, cited previously) in view of Jones (US 6,811,560 B2, cited previously). Brown discloses an expandable hoop support (10; fig.1A) and procedure for opening an artery substantially as claimed. Brown discloses a preformed hoop stent (10) composed of a material formed into a first coil (not shown in figs. however disclosed at col.4, lines 48-50; primary coil), the first coil formed into a second coil (secondary coil; col.4, lines 50-53; shown in figs.) and the coil having memory (fig.1A; col.3, lines 12-19) and the claimed spacing (fig.1A; spacing of 60 shown greater than spacing of 30) and a cylindrical delivery

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means to constrain coil into a linear configuration (col.8, lines 62-65), the delivery means being either a rod fit within the coil (over a guidewire, col.3, lines 21-24; col.4, lines 65-67) or a tube fit over the coil (through a catheter, col.3, lines 21-24; col.8, lines 62-65), and wherein when delivery means is removed in an artery (or flexible tube, as claimed in claim 1 and 8), coil reconfigures into an original preformed configuration (col.3, lines 21-27; col.4, lines 48-67; col.8, line 62-col.9, line 16). Brown's stent is adapted to hold open the vessel (see all figs as the stent anchors in the vessel, thus inherently has a larger diameter than the vessel such that it exerts outward force and stays in place; further, vessels have a variety of sizes and the stent of Brown is capable of placement in an of them, the Brown stent exerting different amounts of force depending on which vessel it is placed. Additionally, Brown's stent is made of an expandable material and will expand to the vessel wall exerting force on the wall inherently due to the self-expanding properties of the material). Brown discloses the stent to have openings (spaces between hoops 62, see fig.1 for example) that allow some flow of blood into a vessel opening or branch vessel (has capability; see fig.1, 7; col.3, lines 40-44; col.5, lines 5-10; col.10, lines 49-62). Brown discloses the expandable hoop and method substantially as claimed however does not disclose the hoop to having a rounded or ball end. Jones teaches in the same field of hoop stent (14), a coil having a rounded end (32) for the purpose of reducing trauma in the vessel (col.2, lines 54-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Brown's hoop stent with Jones teaching of rounded ends of hoop stents in order to provide a more atraumatic hoop stent which decreases the chances of injuring the surrounding vessels. Rounding ends and edges of hoops are well known in the medical art for the purpose of reducing trauma to the patient and also for providing a catch

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mechanism for delivery systems, and the following are cited as evidence: Samson et al. US 6,254,592 B1, see rounded ends 112; Tekulve US 5,797,953 see rounded ends 29, col.4, lines 52-55; Bishop US 2003/0187498 A1, teaches rounding all exposed edges on stents, P0027, P0034.

Claims 1, 3, 4, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al. (US 6,254,592 B1, cited previously) in view of Dubrul (US 6,258,115). Samson discloses an expandable hoop support comprising a preformed hoop having a primary coil shape (fig.1, 2) and a secondary coil shape (fig.3; col.2, lines 57-59), the coil having rounded ends (112), and a cylindrical delivery means (160; fig.8) to constrain the coil into a linear configuration. Samson discloses the hoop support substantially as claimed. Samson discloses a variety of secondary shapes (fig.3; col.3, lines 47-59), however does not disclose the exact spacing shown. Dubrul teaches in the same field of coils (fig.2), the use of larger central spacing than ends of a coil in order to allow for blood flow through certain areas of the coil (paragraph 6 of detailed description). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Samson's coil structure with Dubrul's teaching of coil spacing in order to provide a coil with blood flow where needed by the patient.

Claims 1-4, 9-10 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul (US 6,258,115 B1) in view of Brown (US 6,093,199, cited previously) and further in view of Jones (US 6,811,560, cited previously). Dubrul discloses an expandable hoop support substantially as claimed. Dubrul discloses a hoop support having two ends with a spacing and a central section with a larger spacing for allowing blood flow into a branch vessel. Dubrul disclose the expandable hoop support substantially as claimed however does not disclose the coil to have a primary coil shape (Dubrul only discloses a secondary coil shape), rounded ends on the

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coil, or the delivery means claimed. Brown teaches in the same field of coil for holding open vessels (see figs), the use of primary coils on such structures in order to provide increased strength for better anchoring and further teaches the ability for insertion in a delivery catheter in a linear configuration as claimed, which allows smaller profile for delivery. Further, Jones teaches in the same field of hoop stent (14), a coil having a rounded end (32) for the purpose of reducing trauma in the vessel (col.2, lines 54-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dubrul's expandable hoop with Brown's teaching of use of primary coils on coil stents and delivery means and further with Jones teaching of rounded ends in order to provide a hoop stent with greater strength, lower profile insertion, and atraumatic.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 6,093,199, cited previously) and further in view of Jones (US 6,811,560, cited previously) as applied to claim 9 above, and further in view of Farzin-Nia (US 6,818,076 B1, cited previously). Brown in view of Jones discloses the hoop support substantially as claimed (see above), however does not disclose the support to be multi-filar. Farzin-Nia teaches in the same field of coil structures for vasculature, the use of a multi-filar support (fig.2) for the purpose of improved fatigue resistance (col.1, lines 57-61; col.3, lines 28-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Brown in view of Jones coiled hoop support with Farzin-Nia's teaching of multi-filar on hoop supports in order to provide a coil with improved fatigue resistance in the vessel for longer lasting support in the body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738